

### REMARKS

This document is filed in reply to the Office Action dated July 9, 2007 ("Office Action"). Applicants have amended the specification as suggested by the Examiner to update the status of the parent application. Claim 1 is amended to more clearly set forth the claimed invention. Support for "SEQ ID NO: 1" and "the isolated polypeptide has a higher enzymatic activity than the wild type 1,3-1,4- $\beta$ -D-glucanase" appears at, e.g., page 1, lines 17-22 of the specification. Applicants have also cancelled claim 4 and added new claim 29, support of which can be found in the specification at page 2, last paragraph. No new matter is introduced.

Upon entry of the proposed amendments, claims 1-3 and 5-29 will be pending. Among them, claims 2, 3, 6, 7, 9-11 and 13-28 have been withdrawn from further consideration for covering a non-elected invention. Claims 1, 5, 8, 12, and 29 will be under examination. Reconsideration of this application is requested in view of the following remarks.

#### 35 U.S.C. § 112 Rejection (Written Description)

Claims 1 and 8 were rejected as failed to comply with the written description requirement. See the Office Action, page 3, last paragraph.

Original claim 1 is drawn to an isolated polypeptide comprising the enzymatic catalytic domains of 1,3-1,4- $\beta$ -D-glucanase and excluding the carboxyl terminal 78 amino acid residues of the 1,3-1,4- $\beta$ -D-glucanase. According to the Office Action,

The recitation of "1,3-1,4- $\beta$ -D-glucanase" fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus without providing any definition of the structure features of the species within the genus. ... One skilled in the art therefore cannot ... visualize or recognize the identity of the member of genus.

See page 5, lines 6-9.

Applicants would like to point out that the specification amply describes “1,3-1,4- $\beta$ -D-glucanase.” For example, the specification, at page 1, lines 20-21, describes the sequence of the 1,3-1,4- $\beta$ -D-glucanase, SEQ ID NO: 1. In the sole interest of moving this case forward, Applicants have amended claim 1 to recite “SEQ ID NO: 1.” In view of the above amendments and remarks, Applicants submit that one skilled in the art could clearly visualize or recognize the identity of the member of genus.

The Office Action also asserted that “there is no evidence on the record of the relationship between the structure of the polypeptide of SEQ ID NO: 8 and the structure of any or all recombinant, variant and mutant of any or all polypeptides have 1,3-1,4- $\beta$ -D-glucanase activity.” See the Office Action, page 6, lines 14-17.

Applicants respectfully traverse. SEQ ID NO: 8 is a mutant form of SEQ ID NO: 7, which corresponds to V25-P271 of SEQ ID NO: 1 and has a W203F mutation. See the specification, page 3, lines 11-12, and 16-21. The specification explicitly teaches two catalytic domains of 1,3-1,4- $\beta$ -D-glucanase, i.e., domains A and B, corresponding to aa 28-202 and aa 203-266 of SEQ ID NO: 1. See page 2, last paragraph. The regions corresponding to these two domains are included in both SEQ ID NO: 7 and SEQ ID NO: 8. Clearly, there is evidence on the record of the relationship between the structure of the polypeptide of SEQ ID NO: 8 and the structure of any or all recombinant, variant and mutant of any or all polypeptides have 1,3-1,4- $\beta$ -D-glucanase activity as claimed.

In view of the above amendments and remarks, Applicants submit that claim 1 meets the written description requirement. Claim 8, dependent from claim 1, further specifies the claimed polypeptide as glycosylated. At least for the same reasons above, claim 8 also meets the requirement.

#### 35 U.S.C. § 112 Rejection (Enablement)

According to the Office Action, “[c]laim 21 is rejected” for not comply with the enablement requirement. See page 7, lines 7-9. However, Applicants note that claim 21 was withdrawn for covering a non-elected invention and therefore not under examination.

In view of the Office Action Summary at page 1, Applicants believe that, “by claim 21,” the Office Action referred to claim 1 or 8 and will address these two claims below.

Original claim 1 is drawn to an isolated polypeptide comprising the enzymatic catalytic domains of 1,3-1,4- $\beta$ -D-glucanase and excluding the carboxyl terminal 78 amino acid residues of the 1,3-1,4- $\beta$ -D-glucanase. Apparently rejecting the claims, the Office Action, at page 9, second paragraph, asserted

the art does not provide any teaching or guidance as to (1) which amino acids within a 1,3-1,4- $\beta$ -D-glucanase can be modified and which ones are conserved such that one of skill in the art can make the recited polypeptides having the same biological activity as that of the polypeptide of SEQ ID NO: 8, (2) which segments of SEQ ID NO: 8 or SEQ ID NO: 1 are essential for activity.

The Office Action also asserted that “[n]o correlation between structure and function of having 1,3-1,4- $\beta$ -D-glucanase activity has been presented [in the specification]. There is no information or guidance as to which amino acid residues in the polypeptides of SEQ ID NO: 8 or SEQ ID NO: 2 can be modified and which ones are to be conserved to create a polypeptide displaying the same activity as that of the polypeptides of SEQ ID NO: 1.” See page 10, lines 14-15.

Applicants respectfully traverse. Contrary to the assertions cited above, the specification provides ample teachings about the relationship between the structure and function of the polypeptide of SEQ ID NO: 8 or 1 so that one of skill in the art would know “which amino acids within a 1,3-1,4- $\beta$ -D-glucanase can be modified and which ones are conserved” and be able to “make the recited polypeptides having the same biological activity as that of the polypeptide of SEQ ID NO: 8.” For example, the specification teaches two catalytic domains of 1,3-1,4- $\beta$ -D-glucanase, i.e., domains A and B of SEQ ID NO: 1 or 8. See page 2, last paragraph. Given these teachings, one skilled in the art would know that these two “segments of SEQ ID NO: 8 or SEQ ID NO: 1 are essential for activity.” Accordingly, one of ordinary skill would know to avoid those conserved domains or make only conservative changes there.

As set forth in MPEP 2164, “[t]he enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention.” Further, “[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” See MPEP 2164.01. Here, claim 1 covers functional variants or mutants of 1,3-1,4- $\beta$ -D-glucanase. Techniques for making such variants or mutants include recombinant DNA, mutagenesis, and enzyme. As acknowledged by the Office Action, “enzyme isolation techniques, recombinant and mutagenesis techniques were well known in the art at the time of the invention, e.g., hybridization or mutagenesis, and it is routine in the art to screen for multiple substitutions or multiple modifications.” See page 11, paragraph 1. Further, the specification provides ample general guidance and specific example as to how to make those variants or mutants. See, e.g., page 4, line 28 to page 5, line 28; and page 6, line 4 to page 10, line 2. It also teaches assays for testing such mutants to find those with the activity of 1,3-1,4- $\beta$ -D-glucanase. See page 8, line 30 to page 9, line 27.

In view of the above remarks, Applicants submit that all of the techniques needed to practice the invention were well known at the time the application was filed. Indeed, they are routine procedures within the skill of ordinary workers in this field. Further, as discussed above, Applicants have provided a reasonable amount of guidance (including actual working examples) in the specification as to how to practice the claimed invention. Thus, claim 1 meets the enablement requirement. Claims 5, 8, 12, and 29 depend from claim 1 and further specify particular embodiments. At least for the same reasons, they also meet the enablement requirement.

### 35 U.S.C. § 102 Rejections

Claim 1 was rejected as being anticipated by Teather *et al.*, J. Bacteriology 172(7): 3837-3841 (“Teather”). See the Office Action, page 12, lines 7-10. According to the Office Action, Teather “discloses a 1,3-1,4- $\beta$ -D-glucanase from *F. succinogenes*,

wherein at least 78 amino acid at the C-terminal is deleted... [t]herefore, the reference of Teather *et al.* anticipates claim 1.” See page 12, lines 11-13.

Applicants have amended claim 1. The claim, as amended, is drawn to an isolated polypeptide having the enzymatic catalytic domains of 1,3-1,4- $\beta$ -D-glucanase and excluding the carboxyl terminal 78 amino acid residues of the 1,3-1,4- $\beta$ -D-glucanase. The 1,3-1,4- $\beta$ -D-glucanase is SEQ ID NO: 1, i.e., the wild type 1,3-1,4- $\beta$ -D-glucanase sequence. See page 1, lines 20-1 of the specification. Amended claim 1 also specifies that the claimed isolated polypeptide has a higher enzymatic activity than the wild type 1,3-1,4- $\beta$ -D-glucanase.

Teather describes three *F. succinogenes* 1,3-1,4- $\beta$ -D-glucanase mutants, two of which have the C-terminal 78 amino acids of the wild type enzyme deleted. See, page 3838, right column, last paragraph. Teather further teaches that all of the three mutants have reduced enzymatic activity. More specifically, the three mutants had “about 0.16% of the original value,” “residue activity, 0.01%,” or “no detectable enzyme activity.” See, page 3838, right column, lines 51-60. In other words, all of the three mutants have enzymatic activities substantially lower than that of the wild type 1,3-1,4- $\beta$ -D-glucanase.

In contract, as mentioned above, the isolated polypeptide of amended claim 1 must have an enzymatic activity higher than that of the wild type 1,3-1,4- $\beta$ -D-glucanase. Thus, amended claim 1 is not anticipated by Teather. By the same token, all claims depend from claim 1 are also not anticipated.

### Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any

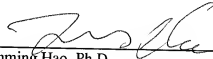
Applicant(s) : Lie-Fen Shyur et al.  
Serial No. : 10/773,455  
Filed : February 6, 2004  
Page : 12 of 12

Attorney Docket No.: 70002-111001  
Client Ref. No.: 14A-890529

claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 70002-111001.

Respectfully submitted,

Date: 10-9-2007

  
\_\_\_\_\_  
Jianming Hao, Ph.D.  
Reg. No. 54,694

Customer No. 69713  
Occhiuti Rohlicek & Tsao LLP  
10 Fawcett Street  
Cambridge, MA 02138  
Telephone: (617) 500-2507  
Facsimile: (617) 500-2499  
11150.doc